



DECLARATION OF CONFORMITY
ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909WA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Manufacturer

Name: Dongguan Jinsihuo Sport Products Company
Limited
Address: No. 13-7, Yiheng South Road, Chiling
Industry Zone, Ching CommunityHoujie Town,
Dongguan, Guangdong, China
SRN: CN-MF-000035270

Product Information

Name: Insole
Model : KSGP0001, KSGP0002, KSGP0004,
KSGP0005, KSGP0006, KSGP0013, KSGP0007,
KSGP0008, KSGP0009, KSGP0010, KSGP0015,
KSGP0019, KSGP0020, KSGP0024, KSGP0025,
KSGP0043, KSGP0045, KSGP0061, KSGP-
SOCK001, KSGP-SOCK002, KSGP-SOCK003,
KSGP-SOCK004, KSGP-SOCK005, SZCP001,
KSGS1806, KSGP-GJ1901, JS2001, JS2002W,
JS2003, JS2208, 21811, SZGP003, KSPG0029,
KSGP0052, KSGP0053, KSGP0054, KSGP0055,
KSGP0056, KSGP0057, KSGP0058, KSGP0059,
JS2301, JS2302, JS2304, JS2305, JS2306, JS2307,
JS2308, JS2309, JS2310, JS2311, JS2312, JS2315,
JS2316, JS2318
ENDN: Y061203
Basic UDI-DI: /
Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-YD61203-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Date: 2023.4.20

Position: GM

Place: Dongguan /China

